

CLAIMS

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1. A vaccine composition which comprises a protein comprising
5 (a) an HIV Tat protein or derivative thereof linked to either (i) a fusion partner
or (ii) an HIV Nef protein or derivative thereof; or
(b) an HIV Nef protein or derivative thereof linked to either (i) a fusion partner
or (ii) an HIV Tat protein or derivative thereof; or
(c) an HIV Nef protein or derivative thereof linked to an HIV Tat protein or
derivative thereof and a fusion partner,
10 in admixture with a pharmaceutically acceptable excipient.
2. A composition as claimed in claim 1 comprising a Tat-Nef fusion protein or
derivative thereof.
15 3. A composition as claimed in claim 1 comprising a Nef-Tat fusion protein or
derivative thereof.
4. A composition according to any one of claims 1 to 3 wherein the derivative
of the Tat protein is a mutated Tat protein.
20 5. A composition according to any one of claims 1 to 4 wherein the derivative
of the Nef protein is a mutated Nef protein.
6. A composition as claimed in any one of claims 1 - 5 wherein the fusion
25 partner is a lipoprotein or derivative thereof.
7. A composition as claimed in claim 6 wherein the lipoprotein is Haemophilus
Influenza B protein D or derivative thereof.
30 8. A composition as claimed in claim 7 wherein the fusion partner comprises
between 100-130 amino acid from the N terminal of Haemophilus Influenza
B protein D.

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9. A composition as claimed in any one of Claims 1 to 8, wherein the Tat protein is the entire Tat protein.
- 5 10. A composition as claimed in any one of Claims 1 to 8, wherein the Nef protein is the entire Nef protein.
- 10 11. A composition as claimed in any one of Claims 1 to 10, wherein the Tat protein is fused to an HIV Nef protein and a fusion partner.
12. A composition as claimed in any one of claims 1 to 11, wherein the protein has a Histidine tail.
- 15 13. A composition as claimed in any one of claims 1 to 12 wherein the protein is carboxymethylated.
14. A composition as claimed in any one of claims 1 to 13, additionally comprising an adjuvant.
- 20 15. A composition as claimed in claim 14, wherein the adjuvant is a TH1 inducing adjuvant.
16. A composition as claimed in claim 14 or 15 which adjuvant comprises monophosphoryl lipid A or a derivative thereof such as 3 de-O-acylated monophosphoryl lipid A.
- 25 17. A composition as claimed in any one of claims 14 to 16 additionally comprising a saponin adjuvant.
- 30 18. A composition as claimed in any one of claims 14 to 17 which additionally comprises an oil in water emulsion.

19. A composition as claimed in any one of claims 1 to 18 further comprising HIV gp160 or its derivative gp120.
20. A protein comprising an HIV Tat protein or derivative thereof linked to an HIV Nef protein or derivative thereof in Nef-Tat or Tat-Nef orientation.
21. A nucleic acid encoding a protein of claim 20.
22. A host transformed with a nucleic acid of claim 21.
23. A host as claimed in claim 22 wherein the host is either *E.coli* or *Pichia pastoris*.
24. A method of producing a protein of claim 20, comprising providing a host as claimed in claim 22 or 23, expressing said protein and recovering the protein.
25. A method of preparing (i) an HIV Nef protein or derivative thereof or (ii) an HIV Tat protein or derivative thereof in *Pichia pastoris* which method comprises the steps of transforming *Pichia pastoris* with DNA encoding said HIV Nef protein or derivative thereof or HIV Tat protein or derivative thereof, expressing said protein and recovering the protein.
26. The method of claim 24 or claim 25 further comprising a carboxymethylation step performed on the expressed protein.
27. A method of producing a vaccine, comprising admixing the protein from any one of claims 24 to 26 with a pharmaceutically acceptable diluent.
28. The method of claim 27 further comprising the addition of HIV gp160 or its derivative gp120.

AMENDED SHEET

- M O S C O W
29. The method of claims 24 to 28 further comprising the addition of an adjuvant, particularly a TH1 inducing adjuvant.
- 5 30. A vaccine composition comprising a recombinant Tat-containing protein formulated with a mixture of 3D-MPL, QS21 and an oil in water emulsion
31. A composition as claimed in claim 30 wherein the oil in water emulsion comprises squalene, polyoxyethylene sorbitan monooleate and α -tocopherol.

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